

Quality Systems Manual (QSM)

Version 5: Update



Presented to:

***EMDQ Workshop 2012
La Jolla, Ca.***

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Report Documentation Page			Form Approved OMB No. 0704-0188	
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1. REPORT DATE MAR 2012	2. REPORT TYPE	3. DATES COVERED 00-00-2012 to 00-00-2012		
4. TITLE AND SUBTITLE Quality Systems Manual (QSM) Version 5: Update		5a. CONTRACT NUMBER		
		5b. GRANT NUMBER		
		5c. PROGRAM ELEMENT NUMBER		
6. AUTHOR(S)		5d. PROJECT NUMBER		
		5e. TASK NUMBER		
		5f. WORK UNIT NUMBER		
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Naval Sea Systems Command,Navy Laboratory Quality & Accreditation Office,1333 Isaac Hull Avenue, SE ,Washington Navy Yard,DC,20376		8. PERFORMING ORGANIZATION REPORT NUMBER		
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)		10. SPONSOR/MONITOR'S ACRONYM(S)		
		11. SPONSOR/MONITOR'S REPORT NUMBER(S)		
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release; distribution unlimited				
13. SUPPLEMENTARY NOTES Presented at the 9th Annual DoD Environmental Monitoring and Data Quality (EDMQ) Workshop Held 26-29 March 2012 in La Jolla, CA.				
14. ABSTRACT				
15. SUBJECT TERMS				
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT Same as Report (SAR)	18. NUMBER OF PAGES 20
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified	19a. NAME OF RESPONSIBLE PERSON	

Agenda



- New Format For QSM version 5
- QSM Changes, Additions & Deletions
- New LCS study
- Who we are: Our Quality Assurance Oversight Subgroup (QAOS)
- Questions

For in much wisdom is much grief; and he that increases knowledge increases sorrow.

Eccles. 1:18 (NIV)

New Format for the QSM

- Will be based on ISO 17025:2005 *General requirements for the competence of testing and calibration laboratories* and Volume 1 of The NELAC Institute (TNI) Standards (September 2009)
- The new QSM is designed for use in conjunction with the ISO and TNI standards. It will be released as a stand alone document.
 - ❖ Copyright issues prevent inclusion of ISO/TNI text
 - ❖ Can freely distribute and post

New Format (cont.)

*****DoD-ELAP and DOECAP programs are expected to remain as currently implemented*****

- DoD/DOE specific language is presented as text to accompany the associated ISO/TNI clauses and is presented as:
 - ❖ Additional requirements
 - ❖ Clarifications of existing text
 - ❖ Guidance
- DoD/DOE requirements have been consolidated to the maximum extent possible, exceptions include:
 - ❖ DoD accreditation program
 - ❖ RAD health/safety programs

New Format (cont.)

Some example language:

4.2.8.4 p) DoD/DOE (Clarification)

The following shall be implemented as a clarification to TNI 4.2.8.4 p):

The procedures for audits and data review shall specify which records must be included in the review.

4.14 DoD/DOE (Requirement)

In addition to clauses 4.14.1 through 4.14.5, the following is required:

4.14.6 The audit schedule shall ensure that all areas of the laboratory are reviewed over the course of one year.

New Format (cont.)

Some example language:

4.13.3 DoD/DOE (Guidance)

The following is guidance to TNI 4.13.3:

Dual storage of records at separate locations is considered an acceptable option for the purpose of protecting records against fire, theft, or loss.

1.5.2.1 DoD/DOE (Requirement)

The following shall be implemented in lieu of TNI 1.5.2.1.f):

- f) For DoD/DOE, the LOD shall be verified quarterly.

What's in a name?

- Expect the combined DoD/DOE document to contain a title that blends both organizations into one due to previous contract awards, procurement policies, and other guidance manuals that reference either QSM or QSAS:

DoD Quality Systems Manual for Environmental Laboratories Version 5.0 & DOE Quality Systems for Analytical Services Version 3.0

Module Overview

- Module 2: General Quality Systems – completed draft version; DoD/DOE Glossary inserted in front; RAD specific definitions to be added.
- Module 3: Asbestos – completed draft version; minor changes to TNI Module.
- Module 4: Chemistry – completed draft version.

Module Overview (cont.)

- **Module 5: Microbiology** – review in progress; no changes expected at this time.
- **Module 6: Radiochemistry** – completed draft version.
- **Module 7: Toxicology** - review completed. No changes expected.

Changes, Deletions, & Additions

- **Module 2 Quality Systems**

Section 4:

- a. Deleted section on Qualifications and Experience Tables for lab personnel
- b. Added Quality Manager has ability to stop unsatisfactory work
- c. Added documents that provide instructions are considered a part of the QS and subject to document control (i.e. cheat sheets)
- d. Added labs shall only report analytes from their scope of accreditation (DoD only)

Changes, Deletions, & Additions (cont.)

- e. Added client feedback requirements that shall be sought (i.e., obsolete methods; method modification required; mismatched detection/action levels; problems with received samples)
- f. Clarified subcontracting:
 - Must meet the requirements of the Standard
 - DoD labs must be DoD-ELAP accredited
 - DOE labs must be approved by appropriate DOE representative
 - Outsourced QS elements (such as data review) must comply with the standard and are subject to review/approval by DoD/DOE

Changes, Deletions, & Additions (cont.)

- g. Added willful avoidance of approved corrective actions may result in loss of DoD accreditation or DOE CAP priority I findings

Section 5:

- a. Storage blanks for volatile analysis analyzed at a minimum every 14 days
- b. Added section on data security: LIMS (requires passwords); spreadsheet calculations (requires verification); software development (requires validation)
- c. Glass syringes for Precision & Bias requires general certificate of uncertainty upon receipt
- d. Added legal Chain of Custody protocols when required and not provided by a State or Federal program

Changes, Deletions, & Additions (cont.)

- **Module 4 Chemistry:**

- a. LOD established at greater than or equal to two times the DL
- b. LOD/LOQ determinations based on scope of accreditation (including prep methods) and can be based on “worst case” basis when multiple cleanup/extractions are used
- c. LOD/LOQ can be verified on a per batch basis (mobile labs/infrequent tests)
- d. Second manufacturer (second source) can be same manufacturer if independently prepared from different source material
- e. Metals analysis with a single point calibration: samples above the quant range (but within the LDR) can be reported if a successful CCV above the sample results is run

Changes, Deletions, & Additions (cont.)

- f. Method Blanks fail if they exceed $\frac{1}{2}$ the LOQ AND are greater than $1/20^{\text{th}}$ the amount measured in any associated sample (or $1/20^{\text{th}}$ the regulatory limit)
- g. For CCVs: the following shall be implemented in lieu of TNI 1.7.2.e):
 - If a CCV fails, the laboratory can immediately analyze two consecutive CCVs
 - Both of these CCVs must meet acceptance criteria in order for the samples to be reported without reanalysis
 - If either of these two CCVs fail or the if the laboratory cannot immediately analyze two CCVs, the associated samples cannot be reported and must be reanalyzed
 - Take corrective action(s) if the above scenario fails until an acceptable CCV is obtained. All affected samples since the last acceptable CCV must be reanalyzed

Proficiency Testing (PT) Samples

- Section 5.9 (PT Requirements) in the Quality Systems Manual has been removed
- Expect to create a new section in Module 2: Quality Systems for proficiency requirements:
 - Based on accreditation for PT providers as ISO Guide 43 (soon to be ISO 17043)
 - Will require PT samples for all analytes that are on a scope of accreditation
 - Will require PT samples twice a year
 - Acceptance/Failure based on program(s) participated in by the PT provider

Will allow for participation of other providers such as the DOE-MAPEP Mixed Analyte Performance Evaluation Program

Other Items of Interest

- Appendix A: References - Removed from the standard
- Appendix E: Reporting Requirements – Update is in progress
- Appendix F: Method Tables – Update in progress
 - ✖ Includes latest EPA update V information, where available
 - ✖ Redundant information eliminated
 - ✖ Previous Method Tables are completed
 - ✖ RADCHEM Method Tables to be added:
 - Alpha Spectroscopy
 - Liquid Scintillation
 - Beta/Gamma Spectroscopy
 - ✖ New Tables (Chemistry):
 - Chemical Warfare Agents (CWA)
 - PFOA/PFOS

LCS Study

- ❖ **Appendix G LCS Study will be removed from the document:**
 - Based on data now over a decade old
 - Based on a limited data set
 - Does not include all analytes of interest
- ❖ **New LCS Study is underway:**
 - Expect all accredited/approved laboratories in the DoD/DOE ultraverse to participate
 - Will require uncensored data sets
 - Contract support will be used to collect/analyze data to ensure confidentiality
 - Results will be published as a stand alone document

Timeline

- Draft version of completed Modules and Tables will be available on DENIX website after our EMDQ Workshop
- Attendees will be emailed a link to the documents
- DoD/DOE work group will continue with unfinished Modules & Tables throughout Spring 2012
- Comments received/variance requests will be evaluated over the summer 2012
- Draft Final document expected by Fall 2012
- Signed DoD/DOE Standard expected in Winter 2013

Environmental Data Quality Workgroup (EDQW)

- The EDQW subgroup that created the new DoD/DOE Standard is composed of the following participants:
 - Navy: Fred McLean (Chair); Janice Willey; William (Ed) Corl
 - Army: Chung-Rei Mao; Charles Stoner
 - Air Force: John (Seb) Gillette
 - DOE: Joe Pardue; Todd Hardt
 - Contractor: Alyssa Wingard

Questions ???



We have answers*

Do not say, “Why were the old days (*of QSM 4.2*) better than these?” For it is not wise to ask such questions.

Eccles. 7:10 (NIV)

Workshop participants are invited to ask questions of the EDQW in the open forum session: Wednesday, March 28th